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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	12 Civ. 3479 (SAS) (FM)
RICHARD HART and MARIE LOUISE TRUDEL-HART, Plaintiffs, v. SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Defendants.	12 Civ. 3560 (SAS) (FM)

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE PORTIONS OF THE EXPERT REPORT AND TESTIMONY OF THOMAS D. BECZE

Defendants Richard Hart and Marie Louise Trudel-Hart (the "Harts") submit this opposition to the motion *in limine* of Plaintiffs Sekisui America Corporation and Sekisui Medical Co., Ltd. ("Plaintiffs") to exclude portions of the expert report and testimony of Thomas D. Becze pursuant to Federal Rule of Evidence 702.

PRELIMINARY STATEMENT

Plaintiffs move to exclude the portions of the report and testimony of the Harts' expert, Thomas D. Becze, rebutting the opinion of Plaintiffs' 510(k) expert, Timothy A. Ulatowski. They contend that Mr. Becze lacks sufficient experience because he has not worked at the United States Food & Drug Administration ("FDA") and that there is no reliable basis for his opinion because he did not read the 510(k) submission at issue. Plaintiffs' contentions are without merit.

Mr. Becze has thirty-three years of experience in quality assurance and regulatory affairs, including composing and submitting over sixty 510(k) notifications. He is more than qualified to render an opinion in rebuttal to Mr. Ulatowski's opinion. Plaintiffs would have known this had they read his *curriculum vitae* or asked him any questions about his 510(k) experience during his deposition.

Mr. Becze proffers his opinion to rebut Mr. Ulatowski's opinion that the 2009 Femtelle 510(k) was "destined to fail." Significantly, Mr. Ulatowski does not base his opinion that the 510(k) was destined to fail on a scientific or technical assessment of the 510(k). Mr. Ulatowski conceded that he does not have the expertise to perform such an assessment.[1] As Mr. Ulatowski does not opine about the contents of the 510(k) itself, in effect conceding that there was nothing wrong with it on its face as written, there is nothing for Mr. Becze to rebut in that regard. Accordingly, Mr. Becze did not need to analyze or opine on the submission as written.

[1] *See* Exh. 4 to Briley Decl. (Transcript of August 15, 2013 Deposition of Timothy A. Ulatowski ("Ulatowski Dep.")) at 47:11-21.

Mr. Ulatowski's opinion that the 510(k) was destined to fail is based entirely on his review of emails regarding the submission among American Diagnostica, Inc. ("ADI") employees, and correspondence between ADI and the FDA relating to FDA requests for further information. Mr. Becze also reviewed this correspondence. Since Mr. Becze wrote his report only to rebut what Mr. Ulatowski said, Mr. Becze's report is appropriate. If the Court finds that a failure to review and address the merits of the 510(k) is significant, that is Mr. Ulatowski's failure, and the remedy is to accord no weight to Mr. Ulatowski's report and testimony.

BACKGROUND

Mr. Becze is an expert in quality assurance and regulatory affairs with thirty-three years of experience. Exh. 1 to Briley Decl. (August 5, 2013 Expert Report of Thomas D. Becze ("Becze Report")), Appendix ("App.") 1 at 1-2. He has "[s]erved as an Expert Witness in both Facility Compliance (GMP/QSR) and Regulatory Affairs (CDRH)" and "as on-site liaison during 107 FDA facility (establishment) inspections." *Id.* He has composed, assembled, and submitted at least seventy-four submissions to the FDA related to medical devices. *Id.* at 2 ("Composition and assembly of 74 IDEs, PMAs, and 510(k)s (medical devices)[2]). Approximately sixty-five of those submissions were 510(k)s, and all but one of those 510(k)s

[2] "A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective … [as] a legally marketed device that is not subject to premarket approval (PMA)." http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm. A PMA "is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification [i.e., a 510(k)], PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses." http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. An IDE is an investigation device exemptions, which is obtained to allow the use of a medical device in clinical studies. *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/.

received FDA clearance.[3] Declaration of Thomas D. Becze in Support of Defendants' Opposition to Plaintiffs' Motion *in Limine* ("Becze Decl.") ¶ 9. Mr. Becze has "advised clients through the entire life cycle of [each] 510(k) (from submission to clearance)." *Id.* ¶ 6. He has "interacted extensively with FDA personnel" in the FDA's Center for Devices and Radiological Health ("CDRH") and its offices *Id.* ¶ 7. The CDRH is responsible for, *inter alia*, "evaluation and clearance or approval of new medical devices [and] ensuring compliance with medical device laws and regulations administered by the FDA[.]" Exh. 2 to Briley Decl. (July 3, 2013 Expert Report of Timothy A. Ulatowski ("Ulatowski Report")) at 3. Mr. Becze's substantial experience is noted in his *curriculum vitae*. *See* Exh. 1 to Briley Decl. (Becze Report), Appendix ("App.") 1.

The Harts proffer Mr. Becze to rebut the opinion of Plaintiffs' 510(k) expert, Timothy A. Ulatowski.[4] Mr. Ulatowski opines that the 2009 Femtelle 510(k) was "destined to fail." *See* Exh. 1 to Briley Decl. (Becze Report) at 4. In so opining, Mr. Ulatowski does not assert that he assessed the Femtelle 510(k) submission and found it to be flawed. Nor does Mr. Ulatowski assert that the 510(k) was so deficient that, had he been the primary reviewer, he would have issued a Refuse to Accept ("RTA"). *See* Exh. 3 to Briley Decl. (Refuse to Accept Policy for 510(k)s, FDA guidance document dated June 30, 1993). Indeed, Mr. Ulatowski concedes that he does not have the "expertise" to perform his own "scientific/technical assessment" of the submission. Exh. 4 to Briley Decl. (Transcript of August 15, 2013 Deposition of Timothy A. Ulatowski ("Ulatowski Dep.")) at 47:11-21. Mr. Ulatowski did not say anything about, or even

[3] One 510(k) was withdrawn at the client's request. *Id.*

[4] Mr. Becze also rebuts the opinions of Plaintiffs' purported FDA expert, Carrie M. Kuehn. *See* Exh. 1 to Briley Decl. (Becze Report) at 4.

cite, the contents or composition of the 510(k) in his report or deposition testimony.[5] *See* Becze Decl. ¶¶ 10-11. Instead, he opines that "there was no possibility that ADI could satisfactorily respond to all the outstanding deficiencies by the time the extension for submitting those deficiencies expired and allow sufficient time for the FDA to review the substantial resubmission before the time expiration in July 2010." Exh. 2 to Briley Decl. (Ulatowski Report) at 33; *see also* Exh. 4 to Briley Decl. (Ulatowski Dep.) at 38:20-39:10. Mr. Ulatowski bases this conclusion entirely on his review of internal ADI correspondence and correspondence between ADI and the FDA relating to requests for further information, not by analyzing the Femtelle 510(k). *See* Exh. 2 to Briley Decl. (Ulatowski Report) at 28-31; *see also* Exh. 5 to Briley Decl. (Chart, Mr. Ulatowski's Citations). As Mr. Ulatowski does not opine that the 510(k) was deficient as written, in effect conceding its sufficiency, Mr. Becze did not need to review or analyze the 510(k) to opine in rebuttal. *See* Exh. 6 to Briley Decl. (Transcript of August 28, 2013 Deposition of Thomas D. Becze ("Becze Dep.")) at 247:10-12. To reach his conclusions, Mr. Becze reviewed the correspondence between ADI and the FDA that Mr. Ulatowski had reviewed. *See id.* at 248:6-12.

Mr. Becze opines in rebuttal that Mr. Ulatowski's conclusion is "pure conjecture" because it "is impossible to predict the outcome of a 510(k) submission" once the FDA accepts it for review. Exh. 1 to Briley Decl. (Becze Report) at 6. As Mr. Becze explains, the only 510(k) submissions that are "destined" to fail are those that are "so bad that [they] will never possibly get through" the review process. Exh. 6 to Briley Decl. (Becze Dep.) at 245:3-7. The FDA

[5] Mr. Ulatowski's report "cites the 2009 Femtelle 510(k) only twice, once in the appendix of documents reviewed and once in a footnote to support his statement, in the chronology section of his report, that the 2009 510(k) was submitted to the FDA." Becze Decl. ¶ 11; *see also* Exh. 4 to Briley Decl. (Ulatowski Dep.) at 47:22-48:21, 49:2-9.

rejects such submissions by issuing an RTA letter.[6] Exh. 1 to Briley Decl. (Becze Report) at 6. If the FDA does not issue an RTA letter, it will request any additional information it deems necessary to complete the file and permit it to make a decision about the submission. *Id.*; *see also* Exh. 2 to Briley Decl. (Ulatowski Report) at 17. It is undisputed that this is what the FDA did in this case. Once the review process begins, there is no way to know whether the medical device will receive 510(k) clearance until the submission "has a chance to go through [the] normal procedure." *See* Exh. 6 to Briley Decl. (Becze Dep.) at 252:3-9; *see also id.* at 245:13-22.

ARGUMENT

Plaintiffs move to preclude Mr. Becze from testifying about the 2009 Femtelle 510(k) on the ground that he "lacks any experience either with the FDA or overseeing the 510(k) submission process" and is thus not qualified. Dkt. 65 at 5. They argue that Mr. Becze does not link his opinions to his experience. *Id.* at 5. They further argue that Mr. Becze does not provide a reliable basis for his opinions because he did not read the 510(k). *Id.* at 4-5. Mr. Becze has the requisite qualifications, links his opinion to his experience, and provides a reliable basis for his rebuttal opinion.

I. Mr. Becze is Qualified to Opine About the 2009 Femtelle 510(k) Submission.

An expert witness is qualified if, by virtue of "knowledge, skill, experience, training, or education," he has relevant "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. "[E]xtensive practical experience" in the relevant field provides the requisite "specialized knowledge." *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995). Mr. Becze is

[6] In his report, Mr. Becze referred to an RTA as a "Refusal File." *See* Exh. 1 to Briley Decl. (Becze Report) at 6. In his deposition, Mr. Becze stated that a "Refusal to File" is the same as an RTA. *See* Exh. 6 to Briley Decl. (Becze Dep.) at 242:9-24.

qualified. Unlike Carrie M. Kuehn, Plaintiffs' FDA compliance expert, Mr. Becze has decades of experience as a quality assurance and regulatory affairs expert, has submitted and assembled dozens of successful 510(k) submissions, and has interacted extensively with high-level FDA personnel regarding 510(k) submissions and compliance issues. *See* Becze Decl. ¶¶ 1, 6-9. The Harts have moved separately to exclude Ms. Kuehn who, unlike Mr. Becze, has never participated in an FDA inspection and whose only training is an online course she took in 2011. *See* Exh. 7 to Briley Decl. (Oct. 18, 2013 Expert Report of Carrie M. Kuehn ("Kuehn Report")) at 1-2.

Mr. Becze's *curriculum vitae* states his extensive experience with the FDA and 510(k) submissions. *See* Exh. 1 (Becze Report, App. 1) at 1-2. Had Plaintiffs asked Mr. Becze about this part of his *curriculum vitae* during his deposition, they would have been aware of his extensive experience. They opted not to ask a single question about Mr. Becze's "experience composing, assembling, and submitting 510(k) notifications." Becze Decl. ¶ 5. Nor did they ask about his thirty-three years of experience as a regulatory affairs expert. Plaintiffs have no basis to assert that Mr. Becze lacks experience with the FDA and the 510(k) submission process, and their assertion is contrary to the facts.

Plaintiffs also have no basis to assert that Mr. Becze does not "link his opinions to his experience[.]" Dkt. 65 at 5. To render his opinion, Mr. Becze "relie[s] on his extensive experience" with 510(k) submissions "to analyze the [process] at issue[.]" *Emig v. Electrolux Home Products Inc.*, 06-CV-4791 (KMK), 2008 WL 4200988 at *8 (S.D.N.Y. Sept. 11, 2008). He utilizes the same methodology to reach his expert conclusions that he utilizes to advise clients in the "real world, … demonstrating a connection between his experience and the process he

used and the conclusions he reached." *Id.* In contrast to Ms. Kuehn, Plaintiffs' FDA compliance expert, Mr. Becze's opinion is connected to the facts and data by more than just his say-so.

Mr. Becze's deposition testimony makes this clear. During his deposition, Mr. Becze testified in detail about the 510(k) submission and review process:

> [A 510(k)] has to be reviewed before someone can determine if it can or cannot be approved. Or given market clearance.
> …
> If ... [a 510(k)] is accepted for review, it's assumed that the report or the document is sufficient to go to the next level, which is to be scheduled for review, and then it's assigned a primary reviewer and usually consults, depending on what the product is.
>
> And then within a 90-day period there has to be a review of the document and usually a letter back to the submitter with a request for additional information or a letter that says we find this to be adequate[,] that your reference to a predicate device is appropriate and you now have market clearance.

Exh. 6 to Briley Decl. (Becze Dep.) at 240:22-243:14.

Mr. Becze's understanding of the 510(k) review process is the product of his extensive experience as a regulatory affairs expert. That Mr. Becze's experience is sufficient to support his specialized knowledge is confirmed by the fact that Mr. Ulatowski's experience led him to the same understanding of the 510(k) review process. *See* Exh. 2 to Briley Decl. (Ulatowski Report) at 17-18.

II. Mr. Becze Provides a Reliable Basis for his Rebuttal Opinion.

To assess the reliability of an expert's proffered opinion, the "court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached[.]" *Id.* Mr. Becze "draws on his expertise of the 510(k) submission process from his [33] years of experience" in the medical device industry. Dkt. 65 at 2. Mr. Becze uses the same methodology employed by Mr. Ulatowski, and bases his conclusions on the same facts and data considered by Mr. Ulatowski. Mr. Ulatowski's opinion is not based on an assessment of the

510(k) itself, which Mr. Ulatowski conceded is beyond his expertise. *See* Exh. 4 to Briley Decl. (Ulatowski Dep.) at 47:11-21. Mr. Ulatowski's opinion that the 2009 Femtelle 510(k) was destined to fail is based entirely on internal ADI correspondence and correspondence between ADI and the FDA. Mr. Becze also bases his opinion on this correspondence. *See* Exh. 6 (Becze Dep.) at 244:18-245:18.

Mr. Becze opines in rebuttal, not as an affirmative expert. The failure to review and opine about merits of the 510(k) is not his failure. As Mr. Ulatowski in effect conceded the adequacy of the 510(k) as written, there was nothing for Mr. Becze to rebut. If a failure to address the adequacy of the 510(k) as written renders an opinion unreliable, that failure is Mr. Ulatowski's. The remedy, therefore, is to accord Mr. Ulatowski's report and testimony no weight.

Mr. Becze also bases his rebuttal opinion on the fact that the FDA did not issue an RTA letter. *See* Exh. 6 (Becze Dep.) at 244:18-245:18. Plaintiffs argue that the RTA mechanism cannot "serve as a reliable basis for [Mr. Becze's] opinion and, in fact, [] highlights his lack of expertise[.]" Dkt. 65 at 5. Plaintiffs' argument misses the point. As Plaintiffs point out, Mr. Becze opines that "a 'Refusal to File' notice [is] the only mechanism by which it is possible to determine that a 510(k) submission [is] destined to fail." *Id.* This is precisely because an RTA "has little, if any, bearing on the merits of a 510(k) submission." *Id.* at 6. The RTA policy clearly distinguishes an acceptance review from a "substantive review" of the 510(k) submission. *See* Exh. 3 to Briley Decl. (Refuse to Accept Policy) at 3, § I(c). If a 510(k) does not pass an acceptance review, it is destined to fail. Put another way, *the FDA would not accept a 510(k) for "substantive review" if the FDA believed it was "destined to fail."* Once a submission is accepted for "substantive review," there is no way to predict whether it will receive clearance.

This is the point of the substantive review: the FDA must determine whether the data provided demonstrates substantial equivalence to a device already on the market. The FDA may request additional information in making this determination; such a request is "not an indication as to whether the FDA will approve the 510(k) application." Exh. 1 to Briley Decl. (Becze Report) at 6. The fact that the FDA continues to request information about a 510(k), as it did for the 2009 Femtelle 510(k), suggests that, contrary to Mr. Ulatowski's opinion, the FDA has not concluded that the submission is destined to fail.

Mr. Becze's acknowledgement that in certain limited circumstances a 510(k) is more likely to fail does not render his opinion unreliable. *See* Dkt. 65 at 3. Mr. Becze's agreement with Plaintiffs' example—that a 510(k) that contains fraudulent information is not likely to receive clearance—has no bearing on the reliability of his opinion. *See* Exh. 6 (Becze Dep.) at 257:13-20.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion *in limine* to exclude portions of the report and testimony of Thomas D. Becze.

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